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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,264	04/24/2001	Ranjani V. Parthasarathy	56286USA4A.003	5359

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,264	PARTHASARATHY ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *25-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The response of 2/19/04 contained arguments and did not amend the claims.

Claims 25-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the response of 8/25/03.

Applicants request for rejoinder is noted, and rejoinder will be considered if the claims being examined on the merits are found allowable. For rejoinder to occur, the claims being rejoined must also be allowable.

Claims examined on the merits are 1-24.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1, 5-16, 20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al (5,861,251) in view of Shultz et al (6,242,235 B1) and Hayes et al (5,721,123) for reasons in the office action of 11/19/03 and for reasons herein.

The claims are drawn to a composition containing an enzyme which can be a polymerase, a dye that inactivates the enzyme and a nonionic or zwitterionic surfactant that inhibits inactivation of the enzyme by the dye. Also claimed is a method of stabilizing an enzyme by combining the surfactant with the enzyme and dye.

Park et al disclose a PCR reagent mixture containing a polymerase, a dye and a nonionic surfactant (col 3, lines 1-42). The nonionic surfactant improves reactivity of the PCR mixture.

Shultz et al disclose stabilizing polymerases with nonionic surfactants (col 6, lines 40-43).

Hayes et al disclose using heat absorptive dyes for enhancing the heating effect of electromagnetic radiation when carrying out the PCR process (col 3, lines 7-36).

It would have been obvious to include in the PCR reagent mixture of Park et al a nonionic surfactant to obtain its function to improve reactivity as taught by Park et al and to obtain its function to stabilize the polymerase as taught by Shultz et al. It would have been further obvious to include in the reagent mixture a heat absorptive dye to obtain its function of enhancing the heating effect of electromagnetic radiation as taught by Hayes et al. The dye of Park et al and/or the heat absorptive dye of Hayes et al would have inherently reduced polymerase activity in the absence of the surfactant. Selecting another surfactant such as a zwitterionic surfactant that functions to stabilize polymerase similar to a nonionic surfactant would have merely required limited routine experimentation and been obvious.

Response to Arguments

It is granted as urged by applicants that the word "dye" does not appear in column 3, lines 1-30 of Park et al. However, "water-soluble dye" is clearly recited at col 3, line 32. It is clear that all of the reagents disclosed by Park et al in col 3 for the PCR are reagents that can be used together in the PCR. Therefore, it is clearly obvious from the teachings of Park et al to use the dye and surfactant together since Park et al teach functions of the dye and surfactant that would have made their combination desirable when performing the PCR.

Applicants urge that the disclosure of a nonionic surfactant by Park et al is isolated and Park et al do not disclose using the surfactant in the disclosed PCR mixture. However, Park et al disclose that nonionic surfactants improve reactivity of the PCR mixture. To obtain this improved reactivity, it would have been obvious to use the nonionic surfactant in a reaction mixture disclosed by Park et al even in the absence of Park et al disclosing a specific PCR mixture containing the surfactant and dye. There is nothing to indicate that Park et al intend to exclude the surfactant from the PCR mixtures disclosed. Convincing evidence has not been provided to establish that dyes used by Park et al will not reduce polymerase activity.

Applicants urge that in Example 6, Park et al disclose that bromophenol blue, xylene cyanole, bromocresol red and cresol red did not decrease the level of the PCR. However, the present specification discloses (paragraph bridging pages 8 and 9) that suitable dyes absorb energy at a wavelength of at least 400 nm. This would appear to include the dyes used by Park et al that are disclosed not to decrease PCR level. Applicants may be using a different method for determining a decrease in enzyme activity due to the dye than used by Park et al for determining a decrease in PCR level. In any event, Park et al disclose that methyl green decreased the PCR level, and the use of this dye in combination with the surfactant would have been obvious.

It is granted as urged by applicants that Shultz et al does not disclose a dye and Hayes et al does not disclose a surfactant. However, these references are combined with the Park et al reference

which suggests a combination of dye and surfactant. The references are applied together and must be considered in combination as a whole rather than each alone. The references clearly provide motivation since the result that will be obtained is taught by the references and will be expected.

Claim Rejections - 35 USC § 103

Claims 2-4, 17-19, 21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 1, 5-16, 20 and 23 above, and further in view of Nadeau et al (5,919,630).

The claims require the dye to be a near-IR dye.

Nadeau et al disclose using near-IR dyes as part of a donor/acceptor dye pair for carrying out the PCR (col 9, line 38, and col 2, line 42).

When modifying the PCR reagent mixture of Park et al as set forth above, it would have been obvious to further include in the PCR reagent mixture a near-IR dye to obtain its function in a donor/acceptor dye pair as taught by Nadeau et al.

Response to Arguments

Applicants urge that Nadeau et al does not disclose a surfactant. However, Nadeau et al is not applied alone, and a surfactant is suggested by Park et al, as well as Shultz et al.

Double Patenting

Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-45 of U.S. Patent No. 6,617,136 B2. Although the conflicting claims

are not identical, they are not patentably distinct from each other because the presently claimed composition and method would have been obvious from the claims of the patent that require a composition containing an enzyme such as a polymerase, a nonionic or zwitterionic surfactant and a near-IR dye

Response to Arguments

Applicants state that an appropriate response will be made when allowable subject matter is indicated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David M. Naff
Primary Examiner
Art Unit 1651

DMN
4/30/04